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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,934	04/21/2004	David G. Gorenstein	UTMB:1022	5106

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
Restriction	10/828,934	GORENSTEIN ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. Applicant's preliminary amendment filed 10/08/2004 is acknowledged and entered. The preliminary amendment amended the instant specification by inserting the required SEQ ID NO identifiers associated with each listed sequence.

2. Claims 1-77 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1-18. Claims 2-10, drawn to an aptamer of a specific SEQ ID NO that binds to a TGF-beta protein, classified in class 435, subclass 23.1. That is each SEQ ID NO of claim 7 is a separate group. For example, SEQ ID NO: 4 correspond to Group 1, SEQ ID NO: 5 correspond to Group 2, and etc. Furthermore, it is noted that SEQ ID NO: 4-21 are nucleotide sequences and SEQ ID NO: 22 is a peptide sequence.

19. Claim 2, drawn to an aptamer of SEQ ID NO: 22 that bind to a TGF-beta protein, classified in class 530, subclass 300+.

20. Claims 12-19, drawn to an aptamer that binds to a TGF-beta receptor, classified in class 435, subclass 4.

21. Claims 20-22, drawn to an aptamer that binds to a TGF-beta ligand and receptor complex, classified in class 435, subclass 7.1.

22. Claims 23-25, drawn to an aptamer that binds to a ligand binding trap, classified in class 536, subclass 24.3.

23. Claims 26-28, drawn to an aptamer that binds to an auxiliary protein, classified in class 435, subclass 6.

24. Claims 29-31, drawn to an aptamer that binds to a Smad protein, classified in class 435, subclass 3.

25. Claims 32-35, drawn to an aptamer that enhances TGF-beta activity, classified in class 530, subclass 300+.

26. Claims 36-40, drawn to an aptamer that inhibits TGF-beta activity, classified in class 530, subclass 300+.

27. Claim 41, drawn to an aptamer that modifies TGF-beta activity, classified in class 530, subclass 300+.

28. Claims 42 and 43, drawn to a method of inhibiting TGF-β activity, classified in class 424, subclass 9.2.

29. Claims 44-52, drawn to a method of quantitating TGF-β level in a sample, classified in class 436, subclass 536.

30. Claims 53-56 and 75-76, drawn to a method of modulating TGF-β signaling, classified in class 436, subclass 537.

31. Claims 57-74, drawn to a method of treating a pathological condition due to increased TGF-β activity, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

4. Claim 1 links inventions of Groups 1-19. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Inventions of Groups 1-27 are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are distinct because they have

materially different design, i.e. different structural features, mode of operation, and/or function. For example, each of groups 1-18 requires the structural features of different nucleotide sequences that are structurally distinct chemical compounds. Group 19 requires the structural features of SEQ ID NO: 22. Group 20 requires an aptamer that binds to a TGF-beta receptor. Group 21 requires the structural features an aptamer that binds to a TGF-beta ligand and receptor complex. Group 22 requires the structural features an aptamer that binds to a ligand binding trap. Group 23 requires the structural features an aptamer that binds to an auxiliary protein. Group 24 requires the structural features an aptamer that binds to a Smad protein. Group 25 requires the structural features an aptamer that enhances TGF-beta activity. Group 26 requires the structural features an aptamer that inhibits TGF-beta activity. Group 27 requires the structural features an aptamer that modifies TGF-beta activity. As a result, these different designs have different function and/or effect. Consequently, the related inventions are distinct, i.e. mutually exclusive, and the art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features. Therefore, these inventions are distinct, and the restriction between these groups is proper.

6. Inventions of Groups 28-31 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and effects, i.e. using different steps, requiring different reagents and/or producing

different results. For example, Group 28 requires the method step of providing to a host in need of therapy a pharmaceutically effective amount of a thioaptamer that specifically binds to and inhibits TGF-β activity. Group 29 requires the method step of contacting a sample with a TGF-β-specific thioaptamer. Group 30 requires the method step of administering to a host a TGF-β specific thioaptamer that modulates the activity through the TGF-β receptor in a dosage effective to reduce activity of the TGF-β. Group 31 requires the method step of administering to a host a TGF-β specific thioaptamer in a pharmaceutically acceptable carrier at a dosage effective to reduce TGF-β activity. These steps require different reagents and/or producing different results. As a result, the different inventions are not disclosed as capable of use together and they have different modes of operation and effects, and the restriction between these groups is proper.

7. Inventions of Groups 1-27 (products) and Group 28-31 (processes) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product such as diagnostic or immunoassay.

8. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods would require completely different searches in

both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. This application contains claims directed to patentably distinct species of the claimed invention for Groups 1-20, 25, and 29-31. Elections of species for ***search purposes*** are required as follows.

11. ***If applicant elected any one of the invention of Groups 1-19***, applicant is required to elect a ***single specific species*** of TGF-beta protein (e.g. claims 2-6).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect ***a single disclosed species*** of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

12. ***If applicant elected the invention of Group 20***, applicant is required to elect a ***single specific species*** of TGF-beta receptor (e.g. claims 13-18).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which

they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect ***a single disclosed species*** of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 12 is generic.

13. ***If applicant elected the invention of Group 25***, applicant is required to elect a ***single specific species*** of binding site (e.g. claims 33-34).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect ***a single disclosed species*** of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 32 is generic.

14. ***If applicant elected the invention of Group 29***, applicant is required to elect from the following patentably distinct species of a)-b).

a) A ***single specific species*** of TGF-beta protein (e.g. claims 47-49).

b) A ***single specific species*** of thioaptamer, i.e. a ***single specific*** SEQ ID NO (e.g. claim 50).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect ***a single disclosed species*** of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 44 is generic.

15. ***If applicant elected the invention of Group 30***, applicant is required to elect from the following patentably distinct species of a)-c).

a) A ***single specific species*** of modulation activity (e.g. claims 54, 55, and 75-77).

b) A ***single specific species*** of thioaptamer, i.e. a ***single specific*** SEQ ID NO (e.g. claim 56).

c) A ***single specific species*** of TGF-β specificity of the thioaptamer (e.g. claims 75-77).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the

species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect ***a single disclosed species*** of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 53 is generic.

16. ***If applicant elected the invention of Group 31***, applicant is required to elect from the following patentably distinct species of a)-c).

a) A ***single specific species*** of TGF-β (e.g. claims 58-60).

b) A ***single specific species*** of thioaptamer, i.e. a ***single specific*** SEQ ID NO (e.g. claim 61).

c) A ***single specific species*** of specificity of the pharmaceutical acceptable carrier (e.g. claims 69-72).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect ***a single disclosed species*** of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 57 is generic.

17. Applicant is advised that ***a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.*** An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. ***If claims are added after the election, applicant must indicate which are readable upon the elected species.*** MPEP § 809.02(a).

19. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

My-Chau T. Tran
August 3, 2006